NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS, CORP. et al., Plaintiffs, v. WOCKHARDT USA LLC and WOCKHARDT LIMITED, Defendants.	Civil Action No. 12-cv-3967 (SDW) (MCA) (Consolidated with Civil Action Nos. 12-cv-4393, 13-cv-1028, 13-cv-2379, and 13-cv-4669) **OPINION** October 23, 2013
NOVARTIS PHARMACEUTICALS, CORP. et al., Plaintiffs, v. SUN PHARMA GLOBAL FZE, et al., Defendants.	
NOVARTIS PHARMACEUTICALS, CORP. et al., Plaintiffs, v. ACTAVIS LLC, et al., Defendants.	

NOVARTIS PHARMACEUTICALS, CORP. et al.,

Plaintiffs,

v.

ACCORD HEALTHCARE INC., et al.,

Defendants.

WIGENTON, District Judge.

Before the Court is Wockhardt USA LLC and Wockhardt Limited's (collectively "Wockhardt") Motion to Dismiss Count II of Plaintiffs' Novartis Pharmaceuticals Corporation ("Novartis"), Novartis Corporation, and Novartis AG ("Plaintiffs") Amended Complaint pursuant to Federal Rule 12(b)(6). Also before the Court are Certain Defendants' Motions to Dismiss including (1) Apotex Corp. and Apotex, Inc.'s (collectively "Apotex") Motion to Dismiss pursuant to Federal Rule 12(b)(6); (2) Pharmaceutics International Inc. ("PII"), Emcure Pharmaceuticals USA, Inc., and Emcure Pharmaceuticals, Ltd.'s (collectively "Emcure") Joint Motion to Dismiss Count II of Plaintiff's Amended Complaint pursuant to Federal Rule 12(b)(6); (3) Agila Specialties Private Ltd. and Strides, Inc.'s (collectively "Strides") Motion to Dismiss Count II of the Amended Complaint pursuant to Federal Rule 12(b)(6); (4) Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), Sun Pharma Global SZE, and Sun Pharmaceutical Industries Ltd.'s (collectively "Sun") Motion to Dismiss Count II of the Amended Complaint pursuant to Federal Rule 12(b)(6); (5) ACS Dobfar Info S.A. and Sagent Pharmaceuticals, Inc.'s (collectively "Sagent") Motion to Dismiss Count II of the Amended Complaint pursuant to Federal Rule 12(b)(6); and (6) Strides's Additional Motion to Dismiss Count II of the Amended Complaint pursuant to Federal Rule 12(b)(6). These six Motions will be referred to as "Certain

Defendants' Motions to Dismiss." Finally before the Court is Apotex's Motion for Judicial Notice of the Food and Drug Administration's ("FDA") Response to Plaintiffs' Citizen Petition.

This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1338(a). Venue is proper under 18 U.S.C. § 1391(b). This Court, having considered the parties' submissions, decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated below, this Court denies Wockhardt's Motion to Dismiss as moot. Additionally, this Court grants, in part, Certain Defendants' Motions to Dismiss Count II with respect to 35 U.S.C. §§ 271(e)(2) and (b), and denies, in part, with respect to 35 U.S.C. § 271(c). This Court grants Apotex's Motion to Dismiss with respect to Count III. Lastly, this Court grants Apotex's Motion for Judicial Notice.

FACTUAL BACKGROUND

Zoledronic acid is a bisphosphonate used to treat various bone diseases. (Am. Compl. ¶¶ 2-4, 55, 57, 71.) Plaintiffs' exclusive patent right to sell zoledronic acid under U.S. Patent No. 4,949,130 expired on March 2, 2013. (Id. ¶ 3.) Plaintiffs' branded products—Zometa® and Reclast®—both have zoledronic acid as their active ingredient. (Id. ¶¶ 55, 57.)

The instant matter relates to three of Plaintiffs' additional patents relating to zoledronic acid. First, Plaintiffs own U.S. Patent No. 8,052,987 ("the '987 Patent") entitled "Method of administering bisphosphonates" which claims a method of using zoledronic acid to treat osteoporosis. (Id. ¶¶ 4, 60.) Second, Plaintiffs own U.S. Patent No. 8,324,189 ("the '189 Patent") entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases" which is directed to oncology methods. (Id. ¶¶ 4, 61.) Third, Plaintiffs own U.S. Patent No. 7,982,241 ("the '241 Patent") entitled "Pharmaceutical products

comprising bisphosphonates" which claims certain approved presentations for zoledronic acid. (Id. ¶¶ 4, 59.)

Plaintiffs allege that Zometa® and Reclast® and their methods of use are covered by one or more claims of the '987, '189, and '241 Patents. (Id. ¶ 62.) Plaintiffs allege that Defendants intend to launch generic versions of zoledronic acid before the expiration of these patents and that Defendants' generic products will infringe their respective patents. (Id. ¶ 5.)

ANDA Process

Under the 1984 Hatch-Waxman Act, companies seeking to bring a generic version of a branded prescription drug can submit an Abbreviated New Drug Application (ANDA) to the FDA. (Id. ¶ 63.) In seeking ANDA approval, applicants have two main options: (1) assert a "paragraph IV certification" claiming that the branded drug patent(s) is/are invalid, unenforceable, and/or will not be infringed pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV); or (2) assert a "section viii carve-out" seeking a label only for uses not covered by the branded product's method of use patents under 21 U.S.C. § 355(j)(2)(A)(viii). (Id. ¶¶ 65-66.)

Here, with regard to the '987 Patent, Certain Defendants seek approval for generic versions of Reclast® and have submitted section viii carve-outs asserting that their proposed labels will not indicate osteoporosis—the patented use for Reclast®. (Id. ¶ 71.) Certain Defendants seek to market their generic Reclast® to treat Paget's disease. (Id.) Certain Defendants have not submitted paragraph IV certifications. (Id.) Plaintiffs allege that Certain Defendants' "representations that their proposed ANDA products will not be offered for sale or sold for the treatment of osteoporosis is knowingly incorrect." (Id. ¶ 72.) According to Plaintiffs, "[o]nly three-tenths percent (0.3%) of patients who take Reclast do so for Paget's disease[ ] . . . and [o]f [ ] 350,000 patients [taking Reclast®], only about 1,000 patients have

Paget's disease." (Id.) Plaintiffs allege that Certain Defendants "have each likely spent substantially more than the total size of the Paget's patient market in order to bring generic Reclast to market." (Id. ¶ 73.)

With regard to the '189 Patent, Plaintiffs claim that Defendants "Actavis, Gland in concert with Apotex, Dr. Reddy's Laboratories, Emcure, PII, Sagent, Sun, Strides, and Wockhardt" provided paragraph IV certifications asserting that the patent is invalid/and or not infringed. (Id. ¶ 69.) With regard to the '241 Patent, Plaintiffs claim that Defendants "Hospira, PII, and Sagent" have filed paragraph IV certifications asserting that the patent is invalid and/or not infringed. (Id. ¶ 68.)

PROCEDURAL HISTORY

Plaintiffs commenced this lawsuit on February 20, 2013 and filed an Amended Complaint on March 15, 2013. Plaintiffs assert the following three Counts in the Amended Complaint: (1) infringement of the '241 Patent; (2) infringement of the '987 Patent; and (3) infringement of the '189 Patent. (Am. Compl. ¶¶ 76-91.) The instant Motions to Dismiss followed.

On May 21, 2013, Magistrate Judge Arleo issued an Order granting Plaintiffs' request to amend their Disclosure of Asserted Claims and consolidating the "zoledronic acid" cases together.[1] This Court affirmed Magistrate Judge Arleo's Order on appeal.

LEGAL STANDARD

Motion to Dismiss

The adequacy of pleadings is governed by Fed. R. Civ. P. 8(a)(2), which requires that a complaint allege "a short and plain statement of the claim showing that the pleader is entitled to relief." This Rule "requires more than labels and conclusions, and a formulaic recitation of the

[1] The lead case is 12-cv-3967 and the member cases are 12-cv-4393, 13-cv-1028, 13-cv-2379, and 13-cv-4669.

elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal citations omitted); see also Phillips v. Cnty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008) (stating that Rule 8 "requires a 'showing' rather than a blanket assertion of an entitlement to relief").

In considering a Motion to Dismiss under Fed. R. Civ. P. 12(b)(6), the Court must "'accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief."' Phillips, 515 F.3d at 231 (quoting Pinker v. Roche Holdings Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (citing Twombly, 550 U.S. at 555). If the "well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint should be dismissed for failing to "show[ ] that the pleader is entitled to relief" as required by Rule 8(a)(2). Id. at 1950.

According to the Supreme Court in Twombly, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his[/her] 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." 550 U.S. at 555 (internal citations omitted). The Third Circuit summarized the Twombly pleading standard as follows: "'stating . . . a claim requires a complaint with enough factual matter (taken

as true) to suggest' the required element." Phillips, 515 F.3d at 234 (quoting Twombly, 550 U.S. at 556).

In Fowler v. UPMC Shadyside, the Third Circuit directed district courts to conduct a two-part analysis. 578 F.3d 203, 210 (3d Cir. 2009). First, the court must separate the factual elements from the legal conclusions. Id. The court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." Id. at 210-11. Second, the court must determine if "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" Id. (quoting Iqbal, 566 U.S. at 679). "In other words, a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Id. (citing Phillips, 515 F.3d at 234-35.)

Motion for Judicial Notice

A court may "judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b)(2). A court "must take judicial notice if a party requests it and the court is supplied with the necessary information." FED. R. EVID. 201(c)(2).

DISCUSSION

I. Wockhardt Motion to Dismiss

Wockhardt argues that "Count II of the 2013 Litigation Corrected Amended Complaint should be dismissed with prejudice because it is duplicative of Count II already pending in the 2012 Litigation." (Wockhardt Br. 5.) The parties completed briefing on this Motion on May 13, 2013. On May 21, 2013, Magistrate Judge Arleo consolidated the 2012 Action and the Present Action and granted Plaintiffs' request to amend the Disclosure of Asserted Claims. On appeal, this Court affirmed Magistrate Judge Arleo's Order regarding Plaintiff's request to amend its

disclosures. In light of the recent developments, this Court finds that Wockhardt's Motion to Dismiss Count II is moot.

II. Apotex's Motion for Judicial Notice

On March 1, 2013, Novartis filed a Citizen Petition with the FDA requesting to block approval of generic versions of Reclast®. (Pls. Judicial Notice Opp. Ex. 1; Apotex Judicial Notice Br. 5, Ex. A.) Specifically, Novartis asked the FDA to "not approve any ANDA seeking approval of a zoledronic acid injectable IV (infusion) product based on omitting protected information in Reclast labeling." (Pls. Judicial Notice Opp. Ex. 1; Apotex Judicial Notice Br. 5, Ex. A.) On March 29, 2013, the FDA approved "two ANDAs which had received tentative approval before the March 1, 2013, expiration of the pediatric exclusivity for zoledronic acid." (Apotex Judicial Notice Br. 5.)

On August 23, 2013, the FDA issued a formal Response to the Citizen Petition concluding that "the [FDA] can approve ANDAs for a zoledronic acid product whose labeling omits information related to the osteoporosis indications." (Id. at 6, Ex B. at 1; see FDA regulatory docket, http://www.regulations.gov, petition docket number FDA-2013-P-0247, made public August 23, 2013, "FDA Response" at 1.)

Apotex requests that this Court take judicial notice of the FDA's Response to Novartis's Citizen Petition which became publicly available on August 23, 2013. (Apotex Judicial Notice Br. 4.) Apotex argues that the FDA Response is relevant to the alleged patent infringement under 35 U.S.C. §§ 271(b), (c), and (e) as discussed in the pending Certain Defendants' Motions to Dismiss. (Apotex Reply 3-6.)

Plaintiffs object to this Court taking judicial notice of the FDA Response and argue that it is irrelevant to the pending Certain Defendants' Motions to Dismiss. (Pls. Judicial Notice Opp.

1.) Plaintiffs contend the FDA Response only addresses whether the generics' labels contain sufficient safety information for treating Paget's disease and not the alleged patent infringement. (Id. at 2.) Furthermore, Plaintiffs argue that Apotex is attempting to pose a new argument under Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984). (Pls. Judicial Notice Opp. 9.) Per Chevron, courts should give deference to agency determinations as to the meaning or reach of a statute. See Chevron, 467 U.S. at 844. Plaintiffs assert that this is a procedurally improper and substantively incorrect argument. (Pls. Judicial Notice Opp. 9.)

This Court finds it appropriate to take judicial notice of the FDA Response to Novartis's Citizen Petition. The FDA Response is a matter of public record that was not available while the parties briefed the pending Motions to Dismiss and is relevant to the issues raised in the Motions. See FED. R. EVID. 201(c)(2) (noting that a court "must take judicial notice if a party requests it and the court is supplied with the necessary information"). In taking judicial notice of the FDA's Response, this Court notes that the FDA's finding is a factor—albeit not dispositive—that supports Certain Defendants' position. It neither presents a new argument nor converts the pending Certain Defendants' Motions to Dismiss into Summary Judgment Motions. Instead, it has become relevant by the FDA's recent ruling and is therefore appropriate to consider.

III. Certain Defendants' Motions to Dismiss

Plaintiffs assert the following three Counts in their Complaint: (1) infringement of the '241 Patent; (2) infringement of the '987 Patent; and (3) infringement of the '189 Patent. (Am. Compl. ¶¶ 76-91.) At issue in the pending Motions to Dismiss are Counts II and III.[2]

[2] It is noted that the return date of Strides's Additional Motion to Dismiss is November 4, 2013. In its two-page brief, Strides notes that "[b]ecause the issues presented here are the same as those previously presented to this Court in the consolidated action, Strides incorporates by reference herein, the arguments presented in support of its[ ] and other Defendants' previously filed motions to dismiss." (Strides Add'l Mot. Br. 1.) Additionally, Strides made clear in its initial Motion to Dismiss that it relied heavily on the arguments set forth by PII/Emcure and Apotex. (See Strides Br. 6-7 ("Strides incorporates by reference the arguments made by [PII]/Emcure and Apotex in support of their motions to dismiss Novartis' induced infringement claims for the '987 patent" and "Strides [ ] incorporates

A. Count II

In Count II, Plaintiffs assert three theories of liability for patent infringement of the '987 Patent. First, Plaintiffs argue that Certain Defendants' ANDAs seeking approval for generics for the same claimed use in the '987 Patent amounts to infringement under § 271(e)(2). Second, Plaintiffs contend that Certain Defendants knowingly and intentionally inducing patients to infringe is a violation of § 271(b). Lastly, Plaintiffs argue that Certain Defendants will continue to infringe on the '987 Patent with generic products that have no substantial, non-infringing use under § 271(c).

1. § 271(e)(2)

Patent infringement under § 271(e)(2)(A) consists of "an application [*i.e.* an ANDA] under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2)(A). The Federal Circuit has noted that "Congress clearly intended to limit actions for infringement of method-of-use patents under § 271(e)(2)(A) to 'controlling use patents,' or patents that claim an approved use of a drug." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1362 (Fed. Cir. 2003). The Federal Circuit held that "a patented method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval to market the drug for that use." AstraZeneca Pharm. LP v. Apotex Corp., 669 F.3d 1370, 1379 (Fed. Cir. 2012) (citing Warner-Lambert, 316

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by reference the arguments and exhibits made in those defendants' briefs [relating to contributory infringement]").) In light of the substantial and comprehensive briefing relating to Count II, this Court is able to make a careful and informed decision on the present Motions to Dismiss before the filing of any reply brief and in advance of the November 4, 2013 return date.

F.3d at 1358-59). Put another way, "an ANDA seeking to market a drug not covered by a composition patent for unpatented methods of treatment cannot infringe under § 271(e)(2)." Id.

a. Plaintiffs' Arguments

Plaintiffs argue that Certain Defendants "submitted an ANDA to sell generic Reclast 'for' osteoporosis in violation of Novartis's patent, notwithstanding that their label is limited to Paget's disease on its face." (Pls. Opp. 20.) Plaintiffs contend that Certain Defendants' section viii labels purporting to carve out instructions relating to treating osteoporosis are improper and misleading. (Id.) In support of this contention, Plaintiffs assert that Certain Defendants "impliedly represent that the generics intend to sell generic Reclast only to treat Paget's, and do not disclose the generics' true intent that generic Reclast be used almost exclusively to treat osteoporosis. (Id. at 20-21.) Relying on AstraZeneca, Plaintiffs argue where a label is "misleading," a claim for infringement is permitted under § 271(e)(2). (Id. at 22); see AstraZeneca, 669 F.3d at 1380.

b. Certain Defendants' Arguments[3]

Certain Defendants argue that Plaintiffs do not state an actionable claim under § 271(e)(2) because none of their proposed labels reference the patented use—treatment of osteoporosis. (See Apotex Br. 2; Emcure 12-13.) Relying on AstraZeneca, Certain Defendants contend that an analysis under § 271(e)(2) is limited to "the scope of the approval sought in the ANDA" and does not extend to speculative uses by others that may occur after the sale. (Apotex Br. 13 (citing AstraZeneca, 669 F.3d at 1379).) They argue that the only approval sought in their ANDAs is for treatment of Paget's disease. (Id. at 14.) Moreover, Certain Defendants note that they submitted section viii certifications carving out any reference to the patented use. (Id.)

[3] This Court notes that Certain Defendants rely on and incorporate by reference the arguments and legal principles set forth in the PII/Emcure and Apotex briefs. (See e.g., Strides Br. 3; Strides Add'l Mot. Br. 1; Sagent Br. 4.)

Relying on Warner-Lambert, Certain Defendants assert that the statutory scheme specifically permits ANDA applicants to seek approval for unpatented drugs and unpatented uses. (Id.) Thus, as Certain Defendants have not sought approval for the treatment of osteoporosis, they argue that there can be no infringement under § 271(e)(2). (See id.; Emcure Br. 13.)

In addition, Certain Defendants argue that their section viii carve-outs are not misleading and instead assert accurate exclusions for the proposed labels. For instance, Apotex argues that "[a] section viii certification is not, and was never intended to be, a representation about how third parties such as doctors will use the product. Instead, it is merely a certification that the application has removed ***from proposed labeling in the ANDA*** all references to the allegedly infringing method-of-use." (Apotex Br. 17 (emphasis in original).) Relying on AstraZeneca, Apotex contends that "a Section viii statement restricting the ANDA to an unpatented use does ***not*** give rise to a claim under § 271(e)(2), regardless of whether the applicant suspects, or expects, or even knows for certain that doctors may also prescribe the generic product for the patented use as to which approval was ***not*** requested." (Id. at 12 (citing AstraZeneca, 669 F.3d at 1380) (emphasis in original).)

Furthermore, under 21 C.F.R. § 314.53(b)(1), patentees must "separately identify each pending or approved method of use and related patent claim." 21 C.F.R. § 314.53(b)(1). Certain Defendants point out that Plaintiffs' Orange Book listing for the '987 Patent indicates treatment for osteoporosis; however, Plaintiffs did not list Paget's disease. (Apotex Br. 15-16.)

c. Analysis

On its face, it appears simple and clear that Plaintiffs cannot assert a viable § 271(e)(2) claim in this matter. According to the Federal Circuit in Warner-Lambert and AstraZeneca, a claim for infringement under § 271(e)(2) must involve filing an ANDA seeking approval for a

patented use. See AstraZeneca, 669 F.3d at 1379 (citing Warner-Lambert, 316 F.3d at 1358-59). Here, Certain Defendants seek approval only for treatment of Paget's disease—a non-patented use. Moreover, Certain Defendants submitted section viii certifications specifically carving out references to osteoporosis—the patented use. With respect to these straight-forward contentions, Plaintiffs do not advance any convincing arguments to the contrary. Thus, upon first glance, recent and well-settled case law supports dismissal of Plaintiffs' claims under § 271(e)(2).

However, digging deeper, the parties' key—and less clear—dispute is whether Certain Defendants' section viii certifications are misleading in stating that the proposed generics would not be used for the treatment of osteoporosis. Both parties rely heavily on AstraZeneca to further their respective positions and both parties recognize that the Federal Circuit did not opine on the viability of a § 271(e)(2) claim in the presence of allegedly improper or misleading statements. 669 F.3d at 1380.

After carefully considering all of the parties' briefs and arguments, this Court does not find Plaintiffs' position convincing. Plaintiffs have not sufficiently pled or demonstrated how Certain Defendants' section viii certifications are misleading or improper. Plaintiffs provide only conclusory statements in support. For instance, Plaintiffs allege that Certain Defendants' carve-out sections are "knowingly incorrect" and that Certain Defendants "intend for there to be substantial use of their generic Reclast products for treatment of osteoporosis." (Am. Compl. ¶¶ 72, 75.) Plaintiffs do not, however, assert that Certain Defendants improperly submitted section viii certifications which misrepresented the actual contents of their proposed labeling.

In considering a motion to dismiss, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler, 578 F.3d at 210-11 (citing Phillips, 515 F.3d at 234-35). Here, even assuming all of the pleaded facts

to be true, Plaintiffs demonstrate a premature and speculative claim, which, at best, is not actionable. See Warner-Lambert, 316 F.3d at 1364 ("Section 271(e)(2) does not encompass 'speculative' claims of infringement."). Additionally, although not dispositive, this Court notes that the FDA Response to Novartis's Citizen Petition supports Certain Defendants' contention that their section viii carve-out provisions excluding osteoporosis indications from their generic product labels are not misleading. Accordingly, this Court finds that Plaintiffs' § 271(e)(2) claim cannot withstand the motion to dismiss stage; thus it is dismissed.

2. § 271(b)

Under § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). In order to prove inducement, a plaintiff must demonstrate that the defendant's "actions induced infringing acts *and* that [it] knew or should have known [its] actions would induce actual infringement." Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) (emphasis in original). That a defendant has "knowledge of the acts alleged to constitute infringement" is not enough. Id. "[P]roof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990). In other words, "[i]nducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent." Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1306 (Fed. Cir. 1999). "While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988).

a. Plaintiffs' Arguments

In support of their § 271(b) claim, Plaintiffs argue that Certain Defendants' "entire business model depends upon doctors using generic Reclast to treat osteoporosis, in violation of Novartis's patent rights." (Pls. Opp. 9.) Plaintiffs contend that "[p]ursuing this business model is the only way the generics can hope to recoup their investment in obtaining FDA approval for their drugs." (Id.) Plaintiffs point to data showing that the generics intend to produce more doses of generic Reclast® than would be necessary for treatment of Paget's disease. (Id. at 9-10.)

Moreover, Plaintiffs allege that Reclast® is used to treat Paget's disease in only three-tenths of one percent (0.3%) of the time while in the remaining ninety-nine and seven-tenths percent (99.7%) it is used to treat osteoporosis. (Am. Compl. ¶ 72.) Plaintiffs argue that Certain Defendants' proposed labeling invites infringement, where the market for Reclast® is dominated by treatment of osteoporosis. (Pls. Opp. 13-14.) Thus, Plaintiffs argue that the Complaint alleges sufficient facts supporting a plausible inference of inducement to infringe. (Id.)

b. Certain Defendants' Arguments

Certain Defendants contend that selling a product without instruction or direction to infringe—such as in this case—does not amount to active infringement. (Apotex Br. 21.) Certain Defendants argue that vicarious liability under § 271(b) requires "some statement from the accused inducer, directed towards the alleged direct infringer, that persuades the direct infringer to engage in activity that the alleged inducer knows would infringe." (Id. at 20.) They argue that the only possible statements to analyze under § 271(b) are their proposed labels. (Id. at 22.) Certain Defendants argue that their labels do not reference osteoporosis—the patented use—and only include an indication for Paget's disease—the unpatented use. (Id.) Accordingly, they argue that Plaintiffs have no viable claim under § 271(b). (Id.)

c. Analysis

This Court finds that Plaintiffs fail to identify any explicit direction or instruction by Certain Defendants that would lead to active infringement under § 271(b). Both parties acknowledge that a claim for induced infringement requires "at least some intent" and that the inducement involve "affirmative steps." (Pls. Opp. 11-12; Apotex Br. 20-21); see Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068 (2011) (holding that "induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement"); DSU Med. Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1305-06 (Fed. Cir. 2006) (articulating that "if an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties"). Here, Certain Defendants' ANDAs seek approval only for Paget's disease and their proposed labels do not mention osteoporosis. Importantly, Plaintiffs have not shown that Certain Defendants have taken "affirmative steps to foster infringement." See DSU Med., 471 F.3d at 1306.

Moreover, Plaintiffs "market realities" arguments are not sufficient to establish intent to induce infringement. In Warner-Lambert, the Federal Circuit noted that "[w]here there are many uses for a product . . . and fewer than 1 in 46 sales of that product are for infringing uses, we are not in a position to infer or not infer intent on the part of [defendant] without any direct evidence." 316 F.3d at 1365. Additionally, the Federal Circuit articulated that "if a physician, without inducement by [defendant], prescribes a use of [a drug] in an infringing manner, [defendant's] knowledge is legally irrelevant." Id. Even in considering Plaintiffs' allegations within the context of the market realties, Plaintiffs have failed to sufficiently plead a claim under § 271(b). Thus, Plaintiffs' claim under § 271(b) is dismissed.

3. § 271(c)

Under § 271(c), contributory infringement occurs where one sells a product "knowing the same to be essentially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c). To state a claim under § 271(c), "a plaintiff must . . . plead facts that allow an inference that the [products] sold or offered for sale have no substantial non-infringing uses." In re Bill of Lading Transmission and Processing Sys. Patent Litig., 681 F.3d 1323, 1337 (Fed. Cir. 2012). "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1362 (Fed. Cir. 2012) (quoting Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1327 (Fed. Cir. 2009)). "In assessing whether a use is substantial, the fact-finder may consider 'the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market.'" Id. (quoting i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010)).

a. Parties' Arguments

Plaintiffs argue that the use of Reclast® to treat Paget's disease—only three-tenths of one percent (0.3%) of the time—is "occasional" and does not amount to "substantial non-infringing use." (Pls. Opp. 18-19.) Certain Defendants argue that "daily occurrences" to treat "at least hundreds and hundreds of cases of Paget's [ ] with Reclast every year" does not render the use insubstantial. (Apotex Br. 24.) Certain Defendants further argue that "[a]n FDA approved indication is necessarily substantial" especially here where Plaintiffs previously sought approval for Paget's disease, conducted clinical trials for this indication, and for which the FDA deemed the product safe and effective. (Id. at 25.)

b. Analysis

For the purposes of these Motions, Plaintiffs have sufficiently pled a claim under § 271(c). This Court finds that determining whether the disputed non-infringing use—treatment of Paget's disease—is "substantial" cannot be done at the pleadings stage. See Braintree Labs., Inc. v. Nephro-Tech, Inc., 31 F. Supp. 2d 921, 924 (D. Kan. 1998) (noting that "[a] claim of contributory infringement involves the resolution of complicated fact questions unsuitable for determination on a motion to dismiss"). Thus, Certain Defendants' Motions to Dismiss relating to the § 271(c) claim are denied.

B. Count III

Count III alleges that several Defendants infringe the '189 Patent. (Am. Compl. ¶¶ 86-91.) Plaintiffs allege that Gland Pharma Ltd. ("Gland")—acting in concert with Apotex—submitted an ANDA regarding a generic of Zometa®. (Id. ¶ 87.) Specifically, Plaintiffs allege that Apotex acted in concert with Gland in manufacturing and selling generic products. (Id. ¶ 14.) Moreover, Plaintiffs allege that Apotex mailed Gland's paragraph IV letter. (Id. ¶ 13.) Plaintiffs argue that "[i]t defies common sense that Gland would entrust Apotex with a mandatory part of the ANDA approval process if Apotex played no role in preparing the ANDA and had nothing to gain if the FDA approved it." (Pls. Opp. 26.)

Apotex moves to dismiss this claim arguing that it did not "submit" the ANDA at issue; that Plaintiffs fail to allege that Apotex was identified in Gland's paragraph IV letter or its ANDA; and that Plaintiffs do not allege that Apotex is an agent for Gland. (Apotex Br. 26-31; Apotex Reply 14-15.) Apotex notes that it submitted a separate and distinct ANDA which did not contain a paragraph IV certification. (Apotex Br. 28.)

With respect to Count III, this Court grants Apotex's Motion to Dismiss without prejudice. It is noted that "[p]arties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family." Cephalon, Inc. v. Watson Pharm., Inc., 629 F. Supp. 2d 338, 349 (D. Del. 2009). Based on the pleadings, there is insufficient evidence to establish that Apotex was "actively involved" or "submitted" the ANDA for a generic Zometa® product in concert with Gland. If discovery leads to information supporting a claim of infringement by Apotex through Gland, Plaintiffs can move to amend. At this stage, Plaintiffs fail to assert a viable claim against Apotex regarding Count III.

CONCLUSION

For the reasons stated above, Wockhardt's Motion to Dismiss is **DENIED** as moot. In addition, Apotex's Motion to Judicial Notice of the FDA response to Plaintiffs' Citizen Petition is **GRANTED**. Furthermore, Certain Defendants' Motions to Dismiss are **GRANTED**, in part, with respect to § 271(e)(2) and § 271(b) of Count II, and **DENIED**, in part, with respect to § 271(c) of Count II. Apotex's Motion to Dismiss with respect to Count III is **GRANTED**.

s/ Susan D. Wigenton
Susan D. Wigenton, U.S.D.J.

cc: Madeline Cox Arleo, U.S.M.J.